Attorney Docket No.: PP19844-0003

-3-

Amendments to the Claims

Please amend Claims 5, 6, 14, 15, 16, 17, 20, 21, 22, 25 and 27. Please add new Claims 28-39. The Claim Listing below will replace all prior versions of the claims in the application:

Claim Listing:

- (original) An HIV DNA vaccine composition comprising
 a nucleic acid expression vector comprising at least one HIV Gag- or Envencoding sequence; and
 PLG.
- 2. (original) The vaccine composition of claim 1, wherein the concentration of PLG is between about 5 and 100 fold greater than the concentration of the nucleic acid expression vector.
- 3. (original) The vaccine composition of claim 2, wherein the concentration of nucleic acid is between about 10 μ g/mL and 5 mg/mL and the concentration of the PLG is between about 100 μ g/mL and 100 mg/mL.
- 4. (original) The vaccine composition of claim 1, wherein the nucleic acid concentration per dose is between approximately 1 μg/dose and 5 mg/dose and the PLG concentration per dose is between approximately 10 μg/dose and 100 mg/dose.
- 5. (currently amended) The vaccine composition of any one of claims 1 to 4 claim 1, as set forth in Table 1 or Table 2.
- 6. (currently amended) The vaccine composition of any one of claims 1 to 4 claim 1, as set forth in column 2 of Table 9.
- 7. (original) An HIV vaccine composition comprising oligomeric gp140 (o-gp140); and a pharmaceutically acceptable excipient.
- 8. (original) The HIV vaccine of claim 7, wherein the concentration of o-gp140 is between about .1 and 10 mg/mL.

Attorney Docket No.: PP19844-0003

-4-

- 9. (original) The HIV vaccine of claim 7, wherein the concentration of o-gp140 per dose is approximately $100 \mu g/dose$.
- 10. (original) The HIV vaccine of claim 7, as set forth in Table 3 or Table 11.
- 11. (original) The HIV vaccine of claim 7, further comprising an adjuvant.
- 12. (original) The HIV vaccine of claim 11, wherein the adjuvant is MF59 or CpG.
- 13. (original) The HIV vaccine of claim 12, wherein the adjuvant is MF59 and MF59 is as set forth in Table 4.
- 14. (currently amended) An HIV vaccine comprising an HIV Env DNA vaccine composition, said HIV Env DNA vaccine composition comprising at least one HIV Env-encoding sequence and PLG according to any one of claims 1 to 6; an HIV Gag DNA vaccine composition, said HIV Gag DNA vaccine composition comprising at least one HIV Gag-encoding sequence and PLG according to any one of claims 1 to 6; and an HIV vaccine composition, said HIV vaccine composition comprising oligomeric gp140 (o-gp140) and a pharmaceutically acceptable excipient according to any one of claims 7 to 13.
- 15. (currently amended) A method of generating an immune response in a subject, said method comprising:
- (a) administering to the subject at least one HIV vaccine composition, said composition according to any of claims 1-14 to the subject comprising: (i) a nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence or (ii) an HIV oligomeric gp 140; and
 - (b) administering to the subject, at a time subsequent to the administering of step (a), at least one HIV vaccine composition, said composition according to any of claims 1 to 14 comprising: (i) a nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence or (ii) an HIV oligomeric gp 140.
- 16. (currently amended) The method of claim 15, wherein step (a) comprises A method of generating an immune response in a subject, said method comprising: (a) administering to said subject at least one HIV DNA vaccine composition comprising a

Attorney Docket No.: PP19844-0003

nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence; according to any of claims 1-6 and step (b) comprises and (b) administering to the subject, at a time subsequent to the administering of step (a), at least one vaccine composition according to any of claims 7-13 comprising HIV oligomeric gp140.

- 17. (currently amended) The method of claim 16, wherein step (a) comprises multiple administrations of <u>said</u> at least one <u>HIV DNA</u> vaccine composition according to claims 1-6 and step (b) comprises multiple administrations of <u>said</u> at least one vaccine composition <u>comprising HIV oligometric gp 140</u> according to any of claims 7-13.
- 18. (original) The method of claim 17, wherein step (a) comprises two or three administrations at one month intervals; step (b) comprises two or three administrations at 1, 2 or 3 month intervals; and the time between the administrations of step (a) and step (b) is 1 to 5 months.
- 19. (currently amended) The method of any of claims 15 to 18 claim 16, wherein step (a) comprises administering at least one HIV Gag <u>DNA</u> vaccine and at least one HIV Env <u>DNA</u> vaccine.
- 20. (currently amended) The method of claim 15 or claim 18, wherein step (b) comprises concurrently administering at least one DNA vaccine according to any of claims 1 6 comprising a nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence and at least one HIV vaccine according to any of claims 7 13 comprising oligomeric gp 140.
- 21. (currently amended) The method of any of claim 20, wherein step (a) comprises administering at least one HIV Gag <u>DNA</u> vaccine and at least one HIV Env <u>DNA</u> vaccine.
- 22. (currently amended) The method of any of claims 15 21 claim 15, wherein at least one administration is intramuscular or intradermal.
- 23. (original) A method of making oligomeric HIV Env gp140 proteins, comprising the steps of

introducing a nucleic acid encoding gp140 into a host cell;

culturing the host cell under conditions such that gp140 is expressed in the cell; and

isolating oligomeric gp140 (o-gp140) protein from the host cell.

- 24. (original) The method of claim 23, wherein the o-gp140 is secreted from the cell and isolated from the cell supernatant.
- 25. (currently amended) A method of making an HIV DNA vaccine according to any of claims 1 6 claim 1, comprising the step of

combining a nucleic acid expression vector comprising a sequence encoding one or more HIV polypeptides with aseptic PLG microparticles such that the nucleic acid binds to the PLG microparticles to form a DNA/PLG HIV vaccine.

- 26. (original) The method of claim 25, further comprising the step of lyophilizing the DNA/PLG HIV vaccines.
- 27. (currently amended) A method of making an HIV vaccine according to any of claims 7-13 claim 7, comprising combining o-gp140 with an adjuvant.
- 28. (new) The HIV vaccine of claim 14, wherein the concentration of PLG is between about 5 and 100 fold greater than the concentration of the nucleic acid expression vector.
- 29. (new) The HIV vaccine of claim 28, wherein the concentration of nucleic acid is between about $10 \mu g/mL$ and 5 mg/mL and the concentration of the PLG is between about $100 \mu g/mL$ and 100 mg/mL.
- 30. (new) The HIV vaccine of claim 14, wherein the concentration of nucleic acid per dose is between approximately 1 μ g/dose and 5 mg/dose and the concentration of the PLG per dose is between about 10 μ g/dose and 100 mg/dose.
- 31. (new) The HIV vaccine of claim 14, wherein the HIV Env DNA vaccine composition component is as set forth in Table 1 or column 2 of Table 9.
- 32. (new) The HIV vaccine of claim 14, wherein the HIV Gag DNA vaccine composition component is as set forth in Table 2 or column 2 of Table 9.

PATENT

Attorney Docket No.: PP19844-0003

-7-

- 33. (new) The HIV vaccine of claim 14, wherein the concentration of o-gp140 is between about 0.1 and 10 mg/mL.
- 34. (new) The HIV vaccine of claim 14, wherein the concentration of o-gp140 per dose is approximately $100 \mu g/dose$.
- 35. (new) The HIV vaccine of claim 14, wherein the HIV vaccine composition component is as set forth in Table 3 or Table 11.
- 36. (new) The HIV vaccine of claim 14, wherein the HIV vaccine composition component further comprising an adjuvant.
- 37. (new) The HIV vaccine of claim 36, wherein the adjuvant is MF59 or CpG.
- 38. (new) The HIV vaccine of claim 37, wherein the adjuvant is MF59 and MF59 is as set forth in Table 4.
- 39. (new) The method of claim 16, wherein at least one administration is intramuscular or intradermal.